JUL 27 2001

K012028

510K SUMMARY – Alliger Ultrasonic Surgical System Model AUSS-5

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMSA 1990 and 21CFR 807.92.

1. Submitter's Identification

Name:	MISONIX, INC.
Address:	1938 New Highway, Farmingdale, NY 11735
Telephone Number:	(631) 694-9555
Contact Person:	Albert F. Clancy Jr.
Date Prepared:	22 June 2001

2. Name of Device

Proprietary Name:	Alliger Ultrasonic Surgical System Model AUSS-5
Common / Usual Name:	Ultrasonic Surgical System Ultrasonic Surgical Aspirator
Classification Name:	Instrument, Ultrasonic Surgical

3. Predicate Device Information

Predicate Devices: Alliger Ultrasonic Surgical System model AUSS-4 and the Cavitron Ultrasonic Surgical Aspirator (CUSA) Model NS-100 Ultrasonic Surgical Aspirator

4. Device Description

The Alliger Ultrasonic Surgical System is comprised of a generator, which feeds a 22.5 kHz electrical signal to a piezoelectric crystals mounted in a hand-held handpiece; the crystals then vibrate at the same frequency. The titanium tip attached to the handpiece amplifies the vibration. An irrigation / aspiration unit is provided to introduce irrigation solution and remove fragmented material and waste liquids from the area.

5. Intended Use:

The Alliger Ultrasonic Surgical System is indicated for use in the fragmentation and aspiration of both soft and hard (e.g.: bone) tissue in the following surgical specialties:

Neurosurgery
Gastrointestinal and Affiliated Organ Surgery
Urological Surgery
Plastic and Reconstructive Surgery
General Surgery
Orthopedic Surgery
Gynecology
External genitalia
- condyloma
- benign tumors (lipomas, fibromas, and leiomyomas)
- malignant primary and metastatic tumors of all types and the following cystic lesions:
  - Bartholin's cysts
  - Vestibular adenitis
  - Inclusion cysts
  - Sebaceous cysts

Abdominal area

any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus.

Thoracic Surgery

Limited pulmonary resection such as segmetectomies, nonanatomical subsegmentectomies, and metastatectomies

6. Comparison to Predicate Device: The Alliger Ultrasonic Surgical Systems are similar in design, material and operating parameters to the CUSA NS-100 Ultrasonic Surgical Aspirator. Although the CUSA NS-100 has a magneto-strictive transducer and the Alliger Ultrasonic Surgical Systems have a piezoelectric transducer, and has been previously determined by the FDA to be substantially equivalent.

7. Discussions of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Output Frequency Measurements
Output Power Measurements (No Load to Maximum Load)
Tip Displacement Measurements
Irrigation Flowrate Measurements (Ultrasound On and Flush Mode)
Life Tests
Vacuum Flowrate and Pressure Measurements
Input Power Measurements
EMI Tests
Dielectric Tests on Mains Circuits
Patient Current Leakage and Patient Sink Current Measurements
Power Line Ground Leakage Measurements
Dielectric Tests on Patient Circuits.

8. Discussions of Clinical Tests Performed

N/A

9. Conclusions

Based upon an analysis of the operating characteristic specifications, Output of Engineering Tests, Hazard Analysis, and Voluntary Consensus Standard Investigations, Misonix, Inc. has concluded that the Alliger Ultrasonic Surgical System Model AUSS-5 is substantially equivalent to both the AUSS-4, and the CUSA Model NS-100 system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2001

Mr. Albert F. Clancy, Jr.
Manager, Quality Assurance/Regulatory Affairs
Misonix, Inc.
1938 New Highway
Farmingdale, New York 11735

Re: K012028
Trade/Device Name: Alliger Ultrasonic Surgical System (Model AUSS-5)
Regulation Number: 878.4400
Regulatory Class: II
Product Code: LFL
Dated: June 22, 2001
Received: June 28, 2001

Dear Mr. Clancy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE

510k Number: K012028

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Thoracic Surgery

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for Mark N. Milleson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012028